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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

POE, MICHAEL I

ART UNIT PAPER NUMBER

1732

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,267

Applicant(s)

PLETZER ET AL.

Examiner

Michael I Poe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 23-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 18, 20 and 22 is/are rejected.
- 7) ☒ Claim(s) 19 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 & 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Amendments

1. Applicant's amendment A filed on January 17, 2003 has been entered. Based upon the entry of this amendment, existing claim 18 has been amended, no existing claims have been canceled, and new claims 23-29 have been added. Claims 1-29 are currently pending.

Election/Restrictions

2. Applicant's election without traverse of Group II, claims 17-22 in Paper No. 8 is acknowledged.

3. Claims 1-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 17-22, drawn to a method of preparing an implantable prosthesis for loading into a delivery stent, classified in class 264, subclass 296.
- II. Claims 23-29, drawn to a prosthesis for endoluminal delivery, classified in class 623, subclass 1.46.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process such as a process wherein the alterations are formed during the molding process of the prosthesis rather than by altering a preformed prosthesis.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with applicant's attorney Todd Wight on October 3, 2003, a provisional election was made without traverse to prosecute the invention of Group I, claims 17-22.

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Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 17, 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,810,879 (Myers et al.) in view of U.S. Patent No. 6,053,938 (Goldmann et al.).

Claims 17, 18 and 22

Myers et al. teach a method of forming an intraluminal stent graft (a method for preparing an implantable prosthesis for loading into a delivery sheath) including providing at least one tubular, diametrically adjustable stent (a stent); affixing a tubular covering of expanded polytetrafluoroethylene to the surface of the stent (with at least one layer of biocompatible material attached thereto); and collapsing the coated stent to a collapsed diameter so that it may be inserted into a delivery assembly (collapsing the prosthesis for loading into the delivery sheath) (claim 15; column 7, lines 29-53; column 3, lines 46-65; column 2, lines 58-67; column 1, lines 8-10).

Myers et al. do not specifically teach altering the surface of the biocompatible layer. However, Goldmann et al. teach a method for pleating a conical, textile vessel prosthesis including pleating (altering the surface of the biocompatible layer) the prosthesis by embossing the surface of the prosthesis while supported on a conical template 8 (the altering step further comprising contacting the prosthesis with a

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marking wheel) or by shrinking the prosthesis so that it conforms to the shape of a template 14 in the form of a round bar having on its surface a slight corrugation or transverse ribs 15 (the step of inserted a grooved mandrel of appropriate diameter into the prosthesis, wherein an interference fit between the mandrel and the prosthesis is establish) (abstract; column 2, lines 10-17; column 3, line 40 – column 4, line 6; column 5, line 51 – column 6, line 20; column 6, lines 50-53). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made and one of ordinary skill would have been motivated to alter the surface of the coated stent in the process of Myers et al. using either of the pleating techniques taught by Goldmann et al. to provide a prosthesis which is able to offer the variation and design possibilities of the hitherto known textile vessel prosthesis (see column 1, line 66 – column 2, line 9 of Goldmann et al.).

11. Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,810,879 (Myers et al.) in view of U.S. Patent No. 4,427,616 (Ketcham) when taken in view of U.S. Patent No. 6,053,938 (Goldmann et al.).

Claims 17 and 20

Myers et al. teach a method of forming an intraluminal stent graft (a method for preparing an implantable prosthesis for loading into a delivery sheath) including providing at least one tubular, diametrically adjustable stent (a stent); affixing a tubular covering of expanded polytetrafluoroethylene to the surface of the stent (with at least one layer of biocompatible material attached thereto); and collapsing the coated stent to a collapsed diameter so that it may be inserted into a delivery assembly (collapsing the prosthesis for loading into the delivery sheath) (claim 15; column 7, lines 29-53; column 3, lines 46-65; column 2, lines 58-67; column 1, lines 8-10).

Myers et al. do not specifically teach altering the surface of the biocompatible layer. However, altering the surface of the coated stent in the process of Myers et al. would be prima facie obvious in view of Ketcham when taken with the teaching of Goldmann et al. Ketcham teaches a process of convoluting thermoplastic tubing without the use of wires including engage a tubing with a mandrel 19 having a plurality of coils and convoluting (altering the surface of the biocompatible layer) the thermoplastic tubing by engaging the teeth 99 of a worm gear 8 with the mandrel such that the thermoplastic tube assumes the shape of mandrel 19 (the altering step further comprises contacting the prosthesis with a pressing comb) (column 4, lines 52-68; column 5, lines 17-34; Figure 4). Although Ketcham teaches using a

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pressing comb to alter the surface of a thermoplastic (more specifically Teflon or PTFE) tube, Ketcham does not specifically teach that the tube may be a prosthesis. In this regard, Goldmann et al. teach a method for pleating a conical, textile vessel prosthesis including pleating (altering the surface of the biocompatible layer) the prosthesis by embossing the surface of the prosthesis while supported on a conical template 8 or by shrinking the prosthesis so that it conforms to the shape of a template 14 in the form of a round bar having on its surface a slight corrugation or transverse ribs 15 (abstract; column 2, lines 10-17; column 3, line 40 – column 4, line 6; column 5, line 51 – column 6, line 20; column 6, lines 50-53). As such, Goldmann et al. shows that it was known at the time the invention was made to alter the surface of prosthesis such as the one taught by Myers et al. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made and one of ordinary skill would have been motivated to alter the surface of the coated stent in the process of Myers et al. using the convoluting technique taught by Ketcham, when taken in view of the teaching of Goldmann et al. that it was known to alter the surfaces of a prosthesis, to provide a prosthesis which is able to offer the variation and design possibilities of the hitherto known textile vessel prosthesis (see column 1, line 66 – column 2, line 9 of Goldmann et al.).

Allowable Subject Matter

12. Claims 19 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

- (1) the prior art of record does not teach or suggested the claimed method for preparing an implantable prosthesis for loading into a delivery stent, as a whole, especially including altering the surface of the biocompatible layer by rotating the prosthesis axially in an incremental fashion, wherein sets of creases are created along the longitudinal axis of the prosthesis at a plurality of axial positions, each aligned with grooves in the mandrel, until the prosthesis has been rotated 360° from the first axial position; and
- (2) the prior art of record does not teach or suggested the claimed method for preparing an implantable prosthesis for loading into a delivery stent, as a whole, especially including

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altering the surface of the biocompatible layer with a pressing comb wherein the pressing comb has teeth spaced distance corresponding to the distance between successive longitudinal articulations of a plurality of longitudinal articulations of the stent and wherein the teeth are adapted to create an alteration in the biocompatible layer between each successive longitudinal articulation.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 3,337,673 (Jeckel), U.S. Patent No. 3,998,919 (Urquhart), U.S. Patent No. 4,124,426 (Saul), U.S. Patent No. 4,876,051 (Campbell et al.), U.S. Patent No. 5,512,033 (Westrum, Jr. et al.), U.S. Patent No. 6,315,791 B1 (Gingras et al.), U.S. Patent No. 6,508,966 (Castro et al.), and German Patent Publication No. DE 2829041 A (Mehler et al.) have been cited of interest to show the state of the art at the time the invention was made.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael I Poe whose telephone number is (703) 306-9170. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianne can be reached on (703) 305-5493. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


Michael Poe/mip


MICHAEL COLAIANNI
PRIMARY EXAMINER